Atty Dkt. No.: IRVN-005CIP USSN: 09/771,263

# **REMARKS**

#### **FORMAL MATTERS:**

Claims 2-5, 7-14, 18-24, and 26-31 were previously pending in the application.

Claims 2-5, 8-14, 18-20, 23, and 27 have been allowed, for which applicants are grateful.

Claims 7, 21, 22, 24, 26, 30, and 31 stand rejected.

Claims 21 and 22 have been reworded, and new claims 32 45 have been added. Support for the amendments to claims 21 and 22 is found throughout the specification, and specifically at, for example, page 15, lines 12-13; page 16, lines 14-16; and page 17, lines 9-19.

Accordingly, claims 2-5, 7-14, 18-24, and 26-45 are now pending and under examination.

No new matter has been added.

Reconsideration and allowance of the application is respectfully requested.

#### **INTERVIEW SUMMARY**

Applicants are grateful to Examiner Yaen for a helpful discussion regarding this application with the undersigned and with Michael Schiff, representative of the licensee, on October 17, 2006. Possible amendments to the claims to distinguish the invention from the McBride patent were discussed. The amendments to previously pending claims presented here are in accordance with what was discussed at the interview. All previously pending claims are believed to be in condition for allowance, notice of which is respectfully requested.

## REJECTION UNDER 35 USC §102

Claims 7, 21-22, 24, 26, and 30-31 stand rejected as being anticipated by U.S. Patent No. 6,551,588 ("McBride"). The Office Action asserts that compositions comprising lymphocyte and tumor associated antigen, and the use of such compositions, are taught in the McBride patent. Applicants respectfully disagree.

The cells used in the McBride composition are from a cell line modified by recombinant DNA technology so as to cause the cells to persistently express the cytokine IL 3 from a transgene place into the cell (see, e.g., claim 9 of McBride). In contrast, the cells used in the invention claimed here are isolated from human donors and compounded into a pharmaceutical composition (see, for example,

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pages 15-21 in the Detailed Description, and Example 1). Thus, they are not from a particular established cell line, and have not been genetically modified with a gene for a cytokine.

So as to make this clear to the reader, independent claims 21-22 are herein amended to state explicitly that the composition is made with naturally occurring human lymphocytes. This means that throughout the process from isolation to administration, the lymphocytes are not modified by recombinant DNA technology so as to introduce a transgene into the genome of the cells.

Withdrawal of this rejection is respectfully requested.

### **NEW CLAIMS**

Claims 32-45 are new, but do not add new matter to the disclosure. These claims encompass embodiments of the invention related to embodiments covered by claims 21-22, but define the composition according to the process by which it is produced. The features recited in these claims can be found inter alia in the specification from' page 15 to page 23, throughout the Examples, and throughout the priority documents — including USSN 08/948,939, now U.S. Patent 6,207,147, and USSN 60/028,548.

These claims refer to embodiments of the invention comprising mononuclear cells and tumor antigen, and reciting the process by which the composition used in treatment has been obtained. Claim 32 and its dependents specify that the composition contains PBMC cells obtained from allogeneic donor(s), in addition to the tumor antigen. Claim 40 and its dependents specify that the composition contains allogeneic tumor cells or extracts, in addition to the PBMC cells. Applicants respectfully submit that these features, in addition to the requirement that the PBMC cells be naturally occurring (i.e., not genetically modified) and other characteristics, distinguish the claimed treatment method from prior art methods.

Examination and allowance of these claims is respectfully requested.

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## CONCLUSION AND REQUEST FOR FURTHER INTERVIEW

The application is believed to be in condition for allowance, in view of the amendments and remarks made herein. In the event the Examiner identifies other matters that need to be addressed, applicants request a further interview by telephone. The Examiner is invited to contact the undersigned at the number provided below.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number IRVN-005CIP.

Respectfully submitted,

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